

REMARKS

The Examiner has required restriction to one of the following inventions under 35 U.S.C. §121:

- Group I. Claims 1-10 drawn to a pharmaceutical composition.
- Group II. Claims 11-22 drawn to a method of treating hepatic and immunological disorders.

Responsive to the Requirement for Restriction, Applicants elect to prosecute the invention of Group I, claims 1-10, drawn to a pharmaceutical composition, with traverse.

Applicants respectfully request reconsideration of the Requirement for Restriction, or in the alternative, modification of the Restriction Requirement to allow prosecution of more than one group of Claims designated by the Examiner in the present Application, for the reasons provided as follows.

Under 35 U.S.C. §121 "two or more independent and distinct inventions ... in one Application may ... be restricted to one of the inventions." Inventions are "'independent'" if "there is no disclosed relationship between the two or more subjects disclosed" (MPEP 802.01). The term "'distinct'" means that "two or more subjects as disclosed are related ... but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE OVER EACH OTHER" (MPEP 802.01) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

Further, under Patent Office Examining Procedures, "[i]f the Search and Examination of an entire Application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988) (emphasis added).

Applicants respectfully submit that the groups designated by the Examiner fail to define pharmaceutical compositions and methods of treating using said compositions, with properties so distinct as to warrant separate Examination and Search. Claims 1-10 are drawn to **pharmaceutical compositions for treating hepatitis and immunological disorders**, and are fundamentally related to Claims 11-22 of Group II, drawn to **methods of treating hepatic disorders and immunological disorders using such compositions**.

Applicants respectfully traverse the restriction for the following reasons. The Examiner alleges that the claims of Group I are the product, whereas the claims of Group II are the process. Applicants assert that the restriction is improper because the claims of Group II do not define a process of preparing or making the compositions of Group I. The claims of Group I are drawn to specific pharmaceutical compositions for treating hepatic disorders and immunological disorders. **The claims of Group II are not process claims directed at how to make or prepare such compositions**, but rather are **method of treatment claims** using the compositions. Moreover, the methods of treating of Group II claims are fundamentally related to the claims of Group I, in that both sets of claims are drawn to compositions and methods of treating hepatic and immunological disorders. For example, the Examiner's attention is drawn in particular to claims 11-17, whereby the claims are drawn to methods of treating hepatic disorders or immunological disorders using the compositions of claim 1. Similarly, claim 1 reads on "pharmaceutical compositions for treating hepatitis or immunological disorders". Applicants respectfully assert that the search for any of the characteristics of the compositions separately classified by the Examiner as the invention of Group I would require an additional search of identical subject matter in the claims of Group II, thus resulting in a duplicate search for the same material.

Applicants respectfully draw the Examiner's attention to the fact that the method of treating claims of Group II are dependent on the composition claims of Group I. Furthermore, the pharmaceutical composition claims of Group I specifically state "pharmaceutical compositions for treating hepatitis and immunological disorders", and the method of treating claims, which also recite use of the compositions for hepatitis and immunological disorders, all depend from claim 1 or depend from intervening claims that depend from claim 1. Thus, a search on the claims of elected Group I, eg. pharmaceutical compositions for treating hepatitis and immunological disorders would require a search on identical subject matter, since the claims of Group II read on methods of treating the same disorders using said compositions.

Accordingly, Applicants respectfully submit that the restriction requirement is improper in that the **claims of Group II are not process claims** but are method of

treating claims. Furthermore, Applicants further assert that a search and examination of elected Group I claims with Group II claims can be made without serious burden, and therefore the Examiner must examine all of the claims, or in the alternative, at least additional claims 11-17, of the Application on the merits.

The Examiner's assertions to the contrary notwithstanding, Applicants respectfully submit that the restriction is improper and that conjoint examination and inclusion of all of the Claims of the present Application would not present an undue burden on the Examiner, and accordingly, withdrawal of the Requirement for Restriction, or, at the least, modification to include claims 11-17 with claims 1-10 of elected Group I is in order.

No fees are believed to be necessitated by the foregoing Response. However, should this be erroneous, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment, or credit any overages.

In view of the above, withdrawal of the Requirement for Restriction is requested, and an early action on the merits of the Claims is courteously solicited.

Respectfully submitted,



Veronica Mallon, Ph.D.
Agent for Applicant(s)
Registration No. 52,491

KLAUBER & JACKSON
411 Hackensack Avenue
Hackensack, New Jersey 07601
(201) 487-5800

Date: December 13, 2004